UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

SEALED	:	**FILED UNDER SEAL PURSUANT TO 31 U.S.C. § 3730(b)(2)**
Plaintiffs,	:	
	:	CIVIL ACTION NO.
vs.	:	
	:	COMPLAINT
SEALED	:	
	:	JURY TRIAL DEMANDED
Defendants.	:	
	:	**DO NOT PLACE IN PRESS BOX**

UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

UNITED STATES OF AMERICA, and The STATES OF ALASKA, CALIFORNIA, COLORADO, CONNECTICUT, DELAWARE, FLORIDA, GEORGIA, HAWAII, IOWA, ILLINOIS, INDIANA, LOUISIANA, MARYLAND, MASSACHUSETTS, MICHIGAN, MINNESOTA, MONTANA, NEVADA, NEW JERSEY, NEW MEXICO, NEW YORK, NORTH CAROLINA, OKLAHOMA, RHODE ISLAND, TENNESEE, TEXAS, VERMONT, VIRGINIA, WASHINGTON, and the DISTRICT OF COLUMBIA, *ex rel.* HISHAM ELZAYAT, M.D., Plaintiff, vs. KONINKLIJKE PHILIPS N.V., PHILIPS NORTH AMERICA LLC, and PHILIPS RS NORTH AMERICA LLC, Defendants.	**FILED UNDER SEAL PURSUANT TO 31 U.S.C. § 3730(b)(2)** COMPLAINT JURY TRIAL DEMANDED **DO NOT PLACE IN PRESS BOX**

Plaintiff-Relator Hisham Elzayat, M.D. ("Relator" or "Dr. Elzayat"), on behalf of the United States of America, the States of Alaska, California, Colorado, Connecticut, Delaware, Florida, Georgia, Hawaii, Illinois, Indiana, Iowa, Louisiana, Maryland, Massachusetts, Michigan, Minnesota, Montana, Nevada, New Jersey, New Mexico, New York, North Carolina, Oklahoma, Rhode Island, Tennessee, Texas, Vermont, Virginia, Washington, and the District of Columbia (collectively "the States"), files this complaint against Defendants Koninklijke Philips N.V.,

Philips North America LLC, and Philips RS North America LLC (collectively, "Philips," or "Defendants") and alleges, based upon personal knowledge, relevant documents, and information and belief, as follows:

I. INTRODUCTION

1. This is an action to recover damages and civil penalties on behalf of the United States of America and the States arising from false and/or fraudulent claims caused to be made by Philips and/or its agents, employees, and co-conspirators in violation of the federal False Claims Act, 31 U.S.C. §§ 3729 *et seq.* ("the Act" or "FCA") and the analogous laws of the States.

2. This matter involves Philips's scheme to knowingly sell dangerously defective medical devices used in the care and treatment of patients covered by government health care programs and private insurers.

3. Philips recently disclosed, on April 26, 2021, that user reports indicated that the polyurethane sound abatement foam ("PE-PUR Foam") in certain of its products—namely, its Bi-Level Positive Airway Pressure ("Bi-Level PAP"), Continuous Positive Airway Pressure ("CPAP"), and mechanical ventilator devices—is susceptible to degradation and can cause adverse health effects. Philips stated that "the [PE-PUR] foam may degrade under certain circumstances, influenced by factors including use of unapproved cleaning methods, such as ozone[], and certain environmental conditions involving high humidity and temperature."

4. On June 14, 2021, Philips issued a recall of certain devices "to address identified potential health risks related to the polyester-based polyurethane (PE-PUR) sound abatement foam component in these devices."

5. Some devices that are part of the recall are CPAP and BiLevel PAP Devices manufactured before April 26, 2021, including the E30 (Emergency Use Authorization);

DreamStation (ASV); DreamStation ST (AVAPS); SystemOne (ASV4); C Series (ASV, S/T, AVAPS); OmniLab Advanced Plus (In-Lab Titration Device); SystemOne (Q series); DreamStation (CPAP, Auto CPAP, BiPAP); DreamStation GO (CPAP, APAP); Dorma 400, 500, (CPAP); and REMStar SE Auto (CPAP). *See* Philips Medical Device recall notification (U.S. only)/field safety notice (International Markets), available at https://www.usa.philips.com/healthcare/e/sleep/communications/src-update. Additional devices that are part of the recall are mechanical ventilators manufactured before April 26, 2021, including Trilogy 100 (Ventilator), Trilogy 200 (Ventilator); Garbin Plus, Aeris, LifeVent (Ventilator); and A-Series BiPAP V30 Auto (Ventilator). *Id.* These devices will be referred to throughout this Complaint as the "Foam-Tainted Devices"[1]

6. Philips has stated that it determined that the "PE-PUR foam may degrade into particles which may enter the device's air pathway and be ingested or inhaled by the user, and the foam may off-gas certain chemicals." Philips also recommended that patients using Philips BiLevel PAP and CPAP Devices stop using them.

7. Philips's attempts to address these critical patient safety issues are too little, too late.

8. Philips knew well in advance of its recent recall and disclosures that the Devices could cause serious adverse health effects, including cancer. Despite this, Philips continued to sell the Foam-Tainted Devices both: (a) to hospitals and other health care facilities and providers that used the devices to provide care and treatment to patients including beneficiaries of government

[1] Philips also included three devices in its recall—the A-Series BiPAP Hybrid A30, A-Series BiPAP A40, and A-Series BiPAP A30—that it represents are "not marketed in US." *Id.* But, to the extent any such devices have been used in the care and treatment of patients covered by government health care programs and private insurers in the United States, however, are included in the Foam-Tainted Devices at issue in this Complaint.

health care programs, including Medicare, state Medicaid programs, TRICARE, and CHAMPVA, and private insurers; and (b) directly to patients, in which case Philips received payment from government health care programs, including Medicare, state Medicaid programs, TRICARE, and CHAMPVA, and private insurers.

9. Philips knowingly kept the defective Devices on the market for as long as it did so that it could buy time to develop replacement versions prior to recalling the first-generation Devices—thereby avoiding any revenue gaps. Philips, in no uncertain terms, put profits over patients.

10. Philips has also knowingly sold, and continues to sell, its dangerously defective ventilator Trilogy EV300 (the "EV300 Device," collectively with the Foam-Tainted Devices, the "Devices") to patients covered by government health care programs and private insurers (and to health care providers for use with such patients). The EV300 Device is not included in the June 14, 2021 recall, but rather, contains a separate defect relating to its operating software. In short, the ventilator's software malfunctions in a way that leads to unwanted changes in air pressure, and thus, patient safety issues resulting from same.

11. Philips's schemes violate the FCA because government health care programs do not reimburse either medical device manufacturers for products that are adulterated or misbranded or health care providers for services to patients using such products. The FCA prohibits, among other things, knowingly causing the presentation of a false or fraudulent claim for payment or approval to the federal government or to a grantee of the federal government. 31 U.S.C. § 3729(a)(1)(A). Any person who violates the FCA is liable for civil penalties, plus three times the amount of the damages the United States sustains. *Id.* § 3729(a)(1).

12. Philips's scheme also violates laws of the States, each of which has enacted false claims act analogous to the federal FCA: the Alaska Medical Assistance False Claim and Reporting Act, Alaska Stat. Ann. §§ 09.58.010 *et seq.*; the California False Claims Act, Cal. Gov't Code §§ 12650 *et seq.*; the California Insurance Frauds Prevention Act, Cal. Ins. Code §§ 1871 *et seq.*; the Colorado Medicaid False Claims Act, Colo. Rev. Stat. §§ 25.5-4-303.5 *et seq.*; the Connecticut False Claims Act, Conn. Gen. Stat. §§ 17b-301a *et seq.*; the Delaware False Claims and Reporting Act, 6 Del. C. §§ 1201 *et seq.*; the Florida False Claims Act, Fla. Stat. Ann. §§ 68.081 *et seq.*; the Georgia State False Medicaid Claims Act, Ga. Code Ann. §§ 49-4-168 *et seq.*; the Hawaii False Claims Law, Haw. Rev. Stat. §§ 661-21 *et seq.*; the Illinois Whistleblower Reward and Protection Act, 740 Ill. Comp. Stat. §§ 175/1 *et seq.*; the Illinois Insurance Claims Fraud Prevention AcI,740ILCS 9211 *et seq.*;the Indiana False Claims and Whistleblower Protection Act, Ind. Code Ann. §§ 5-11-5.5-1 *et seq.*; the Iowa False Claims Act, Iowa Code §§ 685.1 *et seq.*; the Louisiana Medical Assistance Programs Integrity Law, La. Rev. Stat. §§ 46:437.1 *et seq.*; the Maryland False Health Claims Act, Md. Code Ann., Health-Gen. §§ 2-601 *et seq.*; the Massachusetts False Claims Law, Mass. Gen. Laws ch. 12, §§ 5A *et seq.*; the Michigan Medicaid False Claims Act, Mich. Comp. Laws §§ 400.601 *et seq.*; the Minnesota False Claims Act, Minn. Stat. §§ 15C.01 *et seq.*; the Montana False Claims Act, Mont. Code Ann. §§ 17-8-401 *et seq.*; the Nevada False Claims Act, Nev. Rev. Stat. Ann. §§ 357.010 *et seq.*; the New Jersey False Claims Act, N.J. Stat. §§ 2A:32C-1 *et seq.*; the New Mexico Medicaid False Claims Act, N.M. Stat. Ann. §§ 27-14-1 *et seq.*; the New York False Claims Act, N.Y. State Fin. Law §§ 187 *et seq.*; the North Carolina False Claims Act, N.C. Gen. Stat. §§ 1-605 *et seq.*; the Oklahoma Medicaid False Claims Act, Okla. Stat. tit. 63 §§ 5053 *et seq.*; the Rhode Island False Claims Act, R.I. Gen. Laws §§ 9-1.1-1 *et seq.*; the Tennessee False Claims Act, Tenn. Code Ann. §§ 4-18-101 *et seq.*, and the

Tennessee Medicaid False Claims Act, Tenn. Code Ann. §§ 71-5-181 *et seq.*; the Texas Medicaid Fraud Prevention Law, Tex. Hum. Res. Code Ann. §§ 36.001 *et seq.*; the Vermont False Claims Act, 31 Vt. Stats. Ann., Ch. 7, Subch. 8, § 630 *et seq.*, the Virginia Fraud Against Taxpayers Act, Va. Code Ann. §§ 8.01-216.1 *et seq.*; the Washington State Medicaid Fraud False Claims Act, Wash. Rev. Code §§ 74.66.005 *et seq.*; and the District of Columbia False Claims Act, D.C. Code §§ 2-381.01 *et seq.*

13. Accordingly, on behalf of the United States and the States, Plaintiff-Relator Hisham Elzayat seeks to recover all available damages, civil penalties, and other relief for federal and state-law violations alleged in this Complaint in every jurisdiction to which Philips's misconduct has extended.

II. THE PARTIES

14. Plaintiff-Relator Hisham Elzayat, M.D. is an adult individual and resident of Texas. A cardiothoracic surgeon by training, Dr. Elzayat was hired in March 2020 to serve as the Director of Medical Affairs at Philips. In this role, Dr. Elzayat had primary responsibility for all patient safety issues regarding Philips healthcare products and interfacing with government agencies worldwide on same.

15. Defendant Koninklijke Philips N.V. ("Royal Philips") is a Dutch multinational corporation with its principal place of business located in Amsterdam, Netherlands. Royal Philips is the parent company of Philips NA and Philips RS.

16. Defendant Philips North America LLC is a Delaware corporation with its principal place of business located at 222 Jacobs Street, Floor 3, Cambridge, Massachusetts 02141. Philips North America is a wholly-owned subsidiary of Koninklijke Philips N.V. Upon information and

belief, Philips NA manages the operation of Royal Philips' various lines of business, including Philips RS, in North America.

17. Defendant Philips RS North America LLC ("Philips RS") is a Delaware corporation with its principal place of business located at 6501 Living Place, Pittsburgh, Pennsylvania 15296. Philips RS was formerly operated under the business name Respironics, Inc. Royal Philips acquired Respironics in 2008.

III. JURISDICTION AND VENUE

18. The Court has subject matter jurisdiction over this case pursuant to 31 U.S.C. § 3732(a) and 28 U.S.C. §§ 1331 and 1345.

19. Venue is proper in this judicial district pursuant to 31 U.S.C. § 3732(a) and/or 28 U.S.C. § 1391(b).

20. This Court has personal jurisdiction over the defendant under 31 U.S.C. § 3732(a) because the defendants transact business and submitted false or fraudulent claims directly or indirectly to the federal government in this judicial district.

21. Relator has direct and independent knowledge on which the allegations are based, is an original source of this information to the United States, and he has voluntarily provided the information to the United States before filing this action based on the information.

22. This suit is not based on prior public disclosures of allegations or transactions in a criminal, civil or administrative hearing, lawsuit, investigation, audit or report, or from the news media. To the extent that there has been any public disclosure unknown to Relator, he is an original source under 31 U.S.C. § 3730(e)(4).

IV. GOVERNMENT REGULATION OF MEDICAL DEVICES

23. Congress enacted the Medical Device Amendments of 1976, 21 U.S.C. § 360c *et seq*. (2017). ("MDA"), to supplement the Food Drug and Cosmetic Act ("FDCA") and to "provide for the safety and effectiveness of medical devices intended for human uses." Pub. L. No. 94-295, 90 Stat. 539, 539 (May 28, 1976). The MDA conferred greater authority on the Food and Drug Administration ("FDA") to regulate medical devices and to prevent devices lacking evidence of safety and effectiveness from being marketed in the United States.

24. A medical device is defined by law as "an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including any component, part, or accessory, which is . . . (B) intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals . . ." 21 U.S.C. § 321(h)(1)(B).

A. Good Manufacturing Requirements

25. The manufacturer of a medical device that is cleared for marketing is required to comply with good manufacturing requirements in its manufacture of the medical device.

26. The current Good Manufacturing Practice requirements ("cGMP") are set forth in the Quality System Regulation ("QS") for Medical Devices: General Regulation. 21 C.F.R. § 820 (2021).

27. The cGMP requirements "govern the methods used in, and the facilities and controls used for, the design [and] manufacture . . . of all finished devices intended for human use. The requirements in this part are intended to ensure that finished devices will be safe and effective and otherwise in compliance with the [FDCA]." 21 C.F.R. § 820.1(a) (2021).

28. Under the cGMP requirements, a medical device manufacturer must, among other things:

a. "establish and maintain procedures to control the design of the device in order to ensure that specified design requirements are met," 21 C.F.R. § 820.30(a)(1) (2021);

b. "develop, conduct, control, and monitor production processes to ensure that a device conforms to its specifications," 21 C.F.R. § 820.70(a) (2021);

c. "establish and maintain procedures to control product that does not conform to specified requirements," including procedures that "address the identification, documentation, evaluation, segregation, and disposition of nonconforming product," 21 C.F.R. § 820.90(a) (2021);

d. As part of the evaluation of nonconformance, "include a determination of the need for an investigation and notification of the persons or organizations responsible for the nonconformance" and document the evaluation and any investigation, 21 C.F.R. § 820.90(a) (2021); and,

e. "establish and maintain procedures for implementing corrective and preventive action," including analyzing processes and operations to "identify existing and potential causes of nonconforming product, or other quality problems" and "identifying the action(s) needed to correct and prevent recurrence of nonconforming product and other quality problems," 21 C.F.R. §§ 820.100(a)(1), (3) (2021).

29. A manufacturer's failure to comply with cGMP requirements renders a device "adulterated" under section 50l(h) of the FDCA. 21 C.F.R. § 820.1(c) (2021).

B. Reporting Requirements

30. Medical device manufacturers have an obligation to report to the FDA device-related deaths, serious injuries and certain malfunctions. *See* 21 U.S.C. § 360i (2017); 21 C.F.R. 803.1 *et seq* (2021). These reports are called medical device reports or MDRs.

31. Medical device manufacturers must file an MDR with the FDA within 30 days of receiving or otherwise becoming aware of information that reasonably suggests that one of its marketed devices may have caused or contributed to a serious injury, or has malfunctioned and that such device or a similar device marketed by the manufacturer would be likely to cause or contribute to a serious injury if the malfunction were to recur. 21 U.S.C. § 360i (2017); 21 C.F.R.

§ 803.50 (2021). MDRs must be filed within five (5) business days of becoming aware of an MDR reportable event that "necessitates remedial action to prevent an unreasonable risk of substantial harm to the public health." 21 C.F.R. § 803.53(a) (2021).

32. A "serious injury" is one that "is life threatening . . . results in permanent impairment of a body function or permanent damage to a body structure, or . . . necessitates medical or surgical intervention to preclude permanent impairment of a body function or permanent damage to a body structure." 21 U.S.C. § 360i(a)(2) (2017); 21 C.F.R. § 803.3(w) (2021). "Permanent" means "irreversible impairment or damage to a body structure or function, excluding trivial impairment or damage." 21 C.F.R. § 803.3(w)(3)(2021).

33. "Caused or contributed" means that "a serious injury was or may have been attributed to a medical device, or that a medical device was or may have been a factor in a serious injury, including events occurring as a result of: (1) Failure; (2) Malfunction; (3) Improper or inadequate design; (4) Manufacture; (5) Labeling; or (6) User error." *Id*. at § 803.3(c) (2021).

34. A device manufacturer also must submit a written report to the FDA when the manufacturer corrects or removes a device: "(A) to reduce a risk to health posed by the device; or (B) to remedy a violation of the act caused by the device which may present a risk to health." 21 U.S.C. § 360i(g)(1) (2017). These reports must be filed within 10 days of initiating the correction or removal. 21 C.F.R. § 806.10(b) (2021).

35. "Removal" means the "physical removal of a device from its point of use to some other location for repair, modification, adjustment, relabeling, destruction or inspection." 21 C.F.R. § 806.2(j) (2021). "Correction" means the "repair, modification, adjustment, relabeling, destruction or inspection (including patient monitoring) or a device without its physical removal from its point of use to some other location." *Id*. at § 806.2(d). "Risk to health" means either "(1)

[a] reasonable probability that use of, or exposure to, the product will cause serious adverse health consequences or death; or (2) that use of, or exposure to, the product may cause temporary or medically reversible adverse health consequences, or an outcome where the probability of serious adverse health consequences is remote." *Id*. at § 806.2(k).

36. Failure to furnish required material or information required by or under 21 U.S.C. § 360i renders the device "misbranded" under the FDCA. 21 U.S.C. § 352(t) (2020). Thus, a manufacturer's failure to file timely or accurate MDRs or reports of removals or corrections of devices renders the devices misbranded.

C. Recall Requirements

37. A recall involves the removal from the market of a product which presents a risk of injury or is otherwise defective. 21 C.F.R. § 7.40 (2021). Recalls may be conducted on a manufacturer's own initiative, by FDA request or by FDA order. *Id.*; 21 C.F.R. § 810.10 (2021). A manufacturer may recall a device if it presents a risk of injury or gross deception or is otherwise defective. 21 C.F.R. § 7.40 (2021). If a manufacturer fails to initiate a recall, the FDA will request the manufacturer to conduct one if the device presents a risk of injury or gross deception or is otherwise defective. 21 C.F.R. § 7.45 (2021).

V. REIMBURSEMENT OF MEDICAL DEVICES BY FEDERAL AND STATE-FUNDED HEALTH CARE PROGRAMS

A. Medicare.

38. Medicare is a federal health insurance system for people 65 and older and for people under 65 with certain disabilities. At all times relevant hereto, the United States has administered Medicare through the Department of Health and Human Services ("HHS"), and its component agency, the Centers for Medicare and Medicaid Services ("CMS"). Acting through intermediary contractors, CMS has reviewed and approved claims submitted for medical reimbursement by

providers of items and services to Medicare beneficiaries, and made payments to providers using monies allocated by the United States, on those claims which appear to qualify for reimbursement under the Medicare program.

39. For inpatient treatment, reimbursement to treating facilities such as hospitals is governed by Medicare Part A, and reimbursement to health care providers such as doctors is governed by Medicare Part B. *See* 42 U.S.C. §§ 1395c-1395w-4 (2021).

40. For treatment outside of the hospital setting, reimbursement to patients is governed by Medicare Part B.

41. To obtain Medicare reimbursement, providers submit claims using forms identifying by code, among other things, the principal diagnosis of the patient and the procedures and services rendered.

42. Under the Medicare program, "no payment may be made under part A or part B for any expenses incurred for items or services which ... are not reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of the malformed body member." 42 U.S.C. § 1395y(a)(l)(A) (2021).

43. Medical devices that are either adulterated or misbranded within the meaning of the FDCA are "not reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of the malformed body member." *Id*.

B. Medicaid.

44. Medicaid is a federal health insurance system that is administered by the states and is available to low-income individuals and families who meet eligibility requirements determined by federal and state law. Medicaid pays for items and services pursuant to plans developed by the states and approved by HHS through CMS. 42 U.S.C. §§ 1396a(a)-(b) (2021). States pay health

care providers according to established rates, and the federal government then pays a statutorily established share of "the total amount expended ... as medical assistance under the State plan." *See* 42 U.S.C. § 1396b(a)(l) (2021).

45. At all times relevant hereto, the United States has provided funds to Alaska, California, Colorado, Connecticut, Delaware, Florida, Georgia, Hawaii, Illinois, Indiana, Louisiana, Maryland, Massachusetts, Michigan, Minnesota, Montana, Nevada, New Hampshire, New Jersey, New Mexico, New York, North Carolina, Oklahoma, Rhode Island, Tennessee, Texas, Virginia, Wisconsin and the District of Columbia for their Medicaid programs, and HHS, through CMS, has ensured that these states have complied with minimum federal standards in its administration of the Medicaid program.

46. While specific State Medicaid coverage guidelines vary, Medicaid's coverage and reimbursement requirements are generally modeled after Medicare's coverage and require as a condition for reimbursement that services be reasonable and medically necessary.

C. Other Federal and State-Funded Health Care Programs.

47. The federal Government administers other health care programs that include, but are not limited to, TRICARE, CHAMPVA, and the Federal Employee Health Benefit Program.

48. TRICARE, which the United States Department of Defense administers, is a health care program for individuals and dependents affiliated with the armed forces.

49. CHAMPVA, which the United States Department of Veterans Affairs administers, is a health care program for the families of veterans with 100-percent service-connected disabilities.

50. The Federal Employee Health Benefit Program, which the United States Office of Personnel Management administers, provides health insurance for federal employees, retirees, and their survivors.

51. The States have programs providing health care benefits to certain individuals based on those individuals' financial need, employment status, or other factors. This Complaint refers to those programs as "state-funded health care programs."

VI. THE UNITED STATES FALSE CLAIMS ACT

52. The United States False Claims Act prohibits, *inter alia*, the following:

> knowingly presenting (or causing to be presented) to the federal government a false or fraudulent claim for payment or approval; and knowingly making or using (or causing to be made or used) a false record or statement material to a false or fraudulent claim[.]

31 U.S.C. §§ 3729(a)(1)(A), (B).

VII. DEFENDANTS' FRAUDULENT CONDUCT

53. Philips sold the Devices to be utilized for the treatment of patients with sleep, breathing, and/or respiratory conditions.

54. As explained above, the Foam-Tainted Devices include Bi-Level PAP machines, CPAP machines, and mechanical ventilators. Each of these Foam-Tainted Devices contain the PE-PUR Foam susceptible to degradation, disintegration, and inhalation via particulates or gas by patients. Inhalation of these particulates or gases, in turn, causes serious health effects, including cancer.

55. The purported impetus for Philips's April 26, 2021 disclosure and June 14, 2021 recall regarding the issues concerning the PE-PUR Foam in its Foam-Tainted Devices was its recent discovery of these problems.

56. In reality, however, Philips knew about these serious patient safety issues long ago, but did nothing to alert the public, patients, or regulatory authorities. Philips continued to sell the Foam-Tainted Devices to patients covered by government health care programs and private insurers, and to hospitals and other health care providers for use in treating such patients, with the knowledge that countless patients were being exposed to the risk of harm up to and including cancer.

57. Dr. Elzayat was informed of these very issues in May 2020, shortly after onboarding at Philips, and he quickly learned that Philips had knowledge of these serious patient concerns for several years.

58. On May 17, 2020, Laura Beringer, Ph.D., a toxicologist at Philips, spoke with Dr. Elzayat about her investigation of patient safety issues surrounding the PE-PUR Foam in the company's Foam-Tainted Devices.

59. Dr. Beringer informed Dr. Elzayat that she started testing on the Foam-Tainted Devices in 2018 when Philips began receiving complaints from all over the world about patients noticing black particles in the tubing system, mask, and their mouth cavities. Dr. Beringer also informed Dr. Elzayat that Philips had been alerted to these issues as early as 2015 and that Philips hired an external toxicologist, Mike Van Dyke, to contest her conclusions.

60. Dr. Elzayat was immediately concerned by what he learned from Dr. Beringer. He soon thereafter convened his own investigation, studied the materials developed in years prior, and sought to impanel a group of outside, independent medical experts to examine the issues. Dr. Elzayat also immediately escalated his concerns internally, which raised alarms with people within the commercial function at Philips.

61. In his investigation, Dr. Elzayat learned that Dr. Beringer's testing demonstrated that the PE-PUR Foam degraded or disintegrated for a number of possible reasons, including humidity, heat, and/or certain cleaning methods.

62. He also learned that Dr. Beringer's test results caused Philips to initiate "Project Uno" in or around 2019 or early 2020. The goal of Project Uno was to develop replacement versions of the affected Bi-Level PAP machines, CPAP machines, and mechanical ventilators prior to recalling the first-generation Devices in order to prevent Philips from losing substantial sums of market share and money. The replacement devices, which have not yet gone to market, are supposed to be designed with new sound abatement foam. Incredibly, Dr. Elzayat has learned that Philips's supplier has been mixing the new foam with the original PE-PUR Foam, so these new devices will suffer from the same defects unless this is corrected.

63. After receiving internal pushback, Dr. Elzayat finally impaneled the independent medical panel. The panel issued its findings in March 2021 and concluded—in line with Dr. Beringer's conclusions and Dr. Elzayat's suspicions—that the chemical compounds being emitted from the disintegration of the PE-PUR Foam were carcinogenic and that no medical benefit from the products could outweigh the great risk caused by patient exposure.

64. After presentation of the panel's results, Dr. Elzayat implored his superiors—including his boss, Gary Lotz and Philips Chief Medical Officer Jan Kimpen—to report these critical safety issues to the appropriate government agencies and to initiate a recall of the Foam-Tainted Devices. In response, Mr. Lotz and others at Philips only began obstructing Dr. Elzayat's ability to continue working on the issues relating to the Foam-Tainted Devices by holding back information and excluding him from important meetings.

65. Ultimately, however, Dr. Elzayat prevailed upon his superiors and Philips made the April 26, 2021 disclosure and issued the June 14, 2021 recall. This came only after great effort, resolve, and consternation on Dr. Elzayat's part, though.

66. Throughout his investigation, Philips attempted to downplay Dr. Elzayat's findings and conclusions by claiming that the number of reports from patients about the issues was limited. But, this reasoning was not sound: (1) the particulates and gases causing the health effects are typically invisible and patients are left unaware that they are inhaling carcinogens and (2) serious conditions, like cancer, usually develop after years of long-term exposure.

67. The only explanation for Philips's unwillingness to report to government agencies years ago was its desire to delay the recall of the Foam-Tainted Devices in the hope of avoiding lost revenue and market share before the replacement Bi-Level PAP machines, CPAP machines, and mechanical ventilators were ready to go to market.

68. Just the same, Philips remains unwilling to recall the EV300 Device. That particular ventilator has a sensor designed to precisely measure the flow of oxygen (both amount and pressure) delivered to patients. Due to a software defect in that ventilator, however, the flow sensor does not work properly. In some cases, the ventilator functions erratically and causes random and unwanted pressure changes. This has led to adverse events, including one patient death in Texas.

69. Dr. Elzayat has implored Philips to stop selling and recall the EV300 Device as well. He has explained the product's malfunction and made the company aware of related adverse safety events. Philips, however, has rebuffed Dr. Elzayat's attempts and refrained from issuing a recall or maintaining the ship-hold instituted by Dr. Elzayat during the week of June 21, 2021.

70. Philips, again, is prioritizing profits over patient safety.

VIII. SUBMISSION OF FALSE CLAIMS TO THE GOVERNMENT

71. Philips failed to take the required corrective actions with respect to the Devices and, also, failed to file timely and accurate reports with the FDA.

72. Despite Philips's knowledge that it manufactured and sold nonconforming and/or malfunctioning Devices, Philips failed to alert the FDA, physicians and hospitals, or patients about the defects, adverse events, and potential for patient harm.

73. Philips also failed to timely recall the Devices.

74. Philips violated the FDCA by manufacturing the nonconforming, malfunctioning and/or adulterated Devices; by failing to make appropriate disclosures and take appropriate corrective action once it learned of the production problems; by failing to file required reports with the FDA; and by failing to initiate a timely recall.

75. Accordingly, Philips has sold Devices to facilities and patients that were adulterated and/or misbranded, and thus, "not reasonable or necessary for the diagnosis or treatment of illness or injury or to improve the functioning of the malformed body member." 42 U.S.C. § 1395y(a)(l)(A).

76. Where the patient receiving an adulterated and/or misbranded Device (or a medical service using such a Device) was a beneficiary of a government health care program, the user facility and/or patient sought and received payment from federal and state governments for devices and/or services that were not reasonable or necessary. Claims for payment for such devices and services presented to the United States and the States were therefore false under the applicable federal and state False Claims Acts and Defendants knowingly caused their submission by their illegal conduct in violation of the FDCA.

IX. SUBMISSION OF FALSE CLAIMS TO PRIVATE INSURERS IN CALIFORNIA AND ILLINOIS

77. In addition to the false claims that Philips submitted and/or caused to be submitted to government health care programs, which form the basis of Relator's claims under the federal and state False Claims Acts, Defendant likewise submitted and/or caused the submission of false claims to private insurers in California and Illinois.

78. These false claims are actionable under the California Insurance Fraud Prevention Act ("CIFPA") and the Illinois Insurance Claims Fraud Prevention Act ("ICFPA").

X. CAUSES OF ACTION

Count I
Federal False Claims Act: Presentation of False Claims
31 U.S.C. § 3729(a)(1)(A)

79. Relator realleges and incorporates by reference the allegations contained in paragraphs above as though fully set forth herein.

80. This is a claim for treble damages and penalties under the federal False Claims Act.

81. Defendants knowingly caused the presentation of false or fraudulent claims to the United States Government for payment or approval.

82. Relator cannot now identify all of the false claims for payment that Defendants' conduct caused, as numerous separate entities across the country presented the false claims. Relator has no control over such entities and no access to records they possess.

83. The United States Government, unaware of the falsity of the claims that Defendants caused to be made, paid and continues to pay the claims that would not be paid but for Defendants' illegal conduct.

84. Had the United States actually known of the false or fraudulent nature of Defendants' representations and claims, it would have been prohibited by law from making corresponding payments to Defendants.

85. Defendants have damaged, and continue to damage, the United States Government in a substantial amount to be determined at trial.

86. Additionally, the United States Government is entitled to the maximum penalty for each and every violation alleged herein.

Count II
Federal False Claims Act: Using False Statements to Get False Claims Paid
31 U.S.C. § 3729(a)(1)(B)

87. Relator realleges and incorporates by reference the allegations contained in paragraphs above as though fully set forth herein.

88. This is a claim for treble damages and penalties under the federal False Claims Act.

89. Defendants knowingly caused the presentation of false or fraudulent claims to the United States Government for payment or approval.

90. Defendants also knowingly made, used, or caused to be made or used false records or statements material to the payment of these false or fraudulent claims.

91. Relator cannot now identify all of the false claims for payment that Defendants' conduct caused, as numerous separate entities across the country presented the false claims. Relator has no control over such entities and no access to records they possess.

92. The United States Government, unaware of the falsity of the claims that Defendants caused to be made, paid and continues to pay the claims that would not be paid but for Defendants' illegal conduct.

93. Had the United States actually known of the false or fraudulent nature of Defendants' representations and claims, it would have been prohibited by law from making corresponding payments to Defendants.

94. Defendants have damaged, and continue to damage, the United States Government in a substantial amount to be determined at trial.

95. Additionally, the United States Government is entitled to the maximum penalty for each and every violation alleged herein.

Count III
Alaska Medical Assistance False Claim and Reporting Act
Alaska Stat. Ann. §§ 09.58.010

96. Relator realleges and incorporates by reference the allegations contained in paragraphs above as though fully set forth herein.

97. This is a claim for treble damages and penalties under the Alaska Medical Assistance False Claim and Reporting Act.

98. Defendants knowingly caused the presentation of false or fraudulent claims to the Alaska State Government for payment or approval.

99. Relator cannot now identify all of the false claims for payment that Defendants' conduct caused, as numerous separate entities across the state presented the false claims. Relator has no control over such entities and no access to records they possess.

100. The Alaska State Government, unaware of the falsity of the claims that Defendants caused to be made, paid and continues to pay the claims that would not be paid but for Defendants' illegal conduct.

101. Defendants have damaged, and continue to damage, the State of Alaska in a substantial amount to be determined at trial.

102. Additionally, the Alaska State Government is entitled to the maximum penalty for each and every violation alleged herein.

Count IV
California False Claims Act

Cal. Gov't Code §§ 12651(a)(1)-(2)

103. Relator realleges and incorporates by reference the allegations contained in paragraphs above as though fully set forth herein.

104. This is a claim for treble damages and penalties under the California False Claims Act.

105. Defendants knowingly caused the presentation of false or fraudulent claims to the California State Government for payment or approval.

106. Relator cannot now identify all of the false claims for payment that Defendants' conduct caused, as numerous separate entities across the state presented the false claims. Relator has no control over such entities and no access to records they possess.

107. The California State Government, unaware of the falsity of the claims that Defendants caused to be made, paid and continues to pay the claims that would not be paid but for Defendants' illegal conduct.

108. Defendants have damaged, and continue to damage, the State of California in a substantial amount to be determined at trial.

109. Additionally, the California State Government is entitled to the maximum penalty for each and every violation alleged herein.

Count V
California Insurance Frauds Prevention Act
Cal. Gov't Code § 1871

110. Relator realleges and incorporates by reference the allegations contained in paragraphs above as though fully set forth herein.

111. This is a claim for treble damages and penalties under the California Insurance Frauds Prevention Act.

112. Defendants knowingly caused the presentation of false or fraudulent claims to California private insurers for payment or approval.

113. Relator cannot now identify all of the false claims for payment that Defendants' conduct caused, as numerous separate entities across the state presented the false claims. Relator has no control over such entities and no access to records they possess.

114. California private insurers, unaware of the falsity of the claims that Defendants caused to be made, paid and continue to pay the claims that would not be paid but for Defendants' illegal conduct.

115. Defendants have damaged, and continue to damage, California private insurers in a substantial amount to be determined at trial.

116. Additionally, the California State Government is entitled to the maximum penalty for each and every violation alleged herein.

Count VI
Colorado Medicaid False Claims Act
Colo. Rev. Stat. §§ 25.5-4-305(1)(a)–(b)

117. Relator realleges and incorporates by reference the allegations contained in paragraphs above as though fully set forth herein.

118. This is a claim for treble damages and penalties under the Colorado Medicaid False Claims Act.

119. Defendants knowingly caused the presentation of false or fraudulent claims to the Colorado State Government for payment or approval.

120. Relator cannot now identify all of the false claims for payment that Defendants' conduct caused, as numerous separate entities across the state presented the false claims. Relator has no control over such entities and no access to records they possess.

121. The Colorado State Government, unaware of the falsity of the claims that Defendants caused to be made, paid and continues to pay the claims that would not be paid but for Defendants' illegal conduct.

122. Defendants have damaged, and continue to damage, the State of Colorado in a substantial amount to be determined at trial.

123. Additionally, the Colorado State Government is entitled to the maximum penalty for each and every violation alleged herein.

Count VII
Connecticut False Claims Act
Conn. Gen. Stat. §§ 17b-301b(a)(1)-(2)

124. Relator realleges and incorporates by reference the allegations contained in paragraphs above as though fully set forth herein.

125. This is a claim for treble damages and penalties under the Connecticut False Claims Act.

126. Defendants knowingly caused the presentation of false or fraudulent claims to the Connecticut State Government for payment or approval.

127. Relator cannot now identify all of the false claims for payment that Defendants' conduct caused, as numerous separate entities across the state presented the false claims. Relator has no control over such entities and no access to records they possess.

128. The Connecticut State Government, unaware of the falsity of the claims that Defendants caused to be made, paid and continues to pay the claims that would not be paid but for Defendants' illegal conduct.

129. Defendants have damaged, and continue to damage, the State of Connecticut in a substantial amount to be determined at trial.

130. Additionally, the Connecticut State Government is entitled to the maximum penalty for each and every violation alleged herein.

Count VIII
Delaware False Claims and Reporting Act
6 Del C. §§ 1201(a)(1)-(2)

131. Relator realleges and incorporates by reference the allegations contained in paragraphs above as though fully set forth herein.

132. This is a claim for treble damages and penalties under the Delaware False Claims and Reporting Act.

133. Defendants knowingly caused the presentation of false or fraudulent claims to the Delaware State Government for payment or approval.

134. Relator cannot now identify all of the false claims for payment that Defendants' conduct caused, as numerous separate entities across the state presented the false claims. Relator has no control over such entities and no access to records they possess.

135. The Delaware State Government, unaware of the falsity of the claims that Defendants caused to be made, paid and continues to pay the claims that would not be paid but for Defendants' illegal conduct.

136. Defendants have damaged, and continue to damage, the State of Delaware in a substantial amount to be determined at trial.

137. Additionally, the Delaware State Government is entitled to the maximum penalty for each and every violation alleged herein.

Count IX
Florida False Claims Act
Fla. Stat. Ann. §§ 68.082(2)(a)-(b)

138. Relator realleges and incorporates by reference the allegations contained in paragraphs above as though fully set forth herein.

139. This is a claim for treble damages and penalties under the Florida False Claims Act.

140. Defendants knowingly caused the presentation of false or fraudulent claims to the Florida State Government for payment or approval.

141. Relator cannot now identify all of the false claims for payment that Defendants' conduct caused, as numerous separate entities across the state presented the false claims. Relator has no control over such entities and no access to records they possess.

142. The Florida State Government, unaware of the falsity of the claims that Defendants caused to be made, paid and continues to pay the claims that would not be paid but for Defendants' illegal conduct.

143. Defendants have damaged, and continue to damage, the State of Florida in a substantial amount to be determined at trial.

144. Additionally, the Florida State Government is entitled to the maximum penalty for each and every violation alleged herein.

Count X
Georgia State False Medicaid Claims Act
Ga. Code Ann. §§ 49-4-168.1(a)(1)-(2)

145. Relator realleges and incorporates by reference the allegations contained in paragraphs above as though fully set forth herein.

146. This is a claim for treble damages and penalties under the Georgia State False Medicaid Claims Act.

147. Defendants knowingly caused the presentation of false or fraudulent claims to the Georgia State Government for payment or approval.

148. Relator cannot now identify all of the false claims for payment that Defendants' conduct caused, as numerous separate entities across the state presented the false claims. Relator has no control over such entities and no access to records they possess.

149. The Georgia State Government, unaware of the falsity of the claims that Defendants caused to be made, paid and continues to pay the claims that would not be paid but for Defendants' illegal conduct.

150. Defendants have damaged, and continue to damage, the State of Georgia in a substantial amount to be determined at trial.

151. Additionally, the Georgia State Government is entitled to the maximum penalty for each and every violation alleged herein.

Count XI
Hawaii False Claims Act
Haw. Rev. Stat. §§ 661-21(a)(1)-(2)

152. Relator realleges and incorporates by reference the allegations contained in paragraphs above as though fully set forth herein.

153. This is a claim for treble damages and penalties under the Hawaii False Claims Act.

154. Defendants knowingly caused the presentation of false or fraudulent claims to the Hawaii State Government for payment or approval.

155. Relator cannot now identify all of the false claims for payment that Defendants' conduct caused, as numerous separate entities across the state presented the false claims. Relator has no control over such entities and no access to records they possess.

156. The Hawaii State Government, unaware of the falsity of the claims that Defendants caused to be made, paid and continues to pay the claims that would not be paid but for Defendants' illegal conduct.

157. Defendants have damaged, and continue to damage, the State of Hawaii in a substantial amount to be determined at trial.

158. Additionally, the Hawaii State Government is entitled to the maximum penalty for each and every violation alleged herein.

Count XII
Illinois Whistleblower Reward and Protection Act
740 Ill. Comp. Stat. §§ 175/3(a)(1)(A)-(B)

159. Relator realleges and incorporates by reference the allegations contained in paragraphs above as though fully set forth herein.

160. This is a claim for treble damages and penalties under the Illinois Whistleblower Reward and Protection Act.

161. Defendants knowingly caused the presentation of false or fraudulent claims to the Illinois State Government for payment or approval.

162. Relator cannot now identify all of the false claims for payment that Defendants' conduct caused, as numerous separate entities across the state presented the false claims. Relator has no control over such entities and no access to records they possess.

163. The Illinois State Government, unaware of the falsity of the claims that Defendants caused to be made, paid and continues to pay the claims that would not be paid but for Defendants' illegal conduct.

164. Defendants have damaged, and continue to damage, the State of Illinois in a substantial amount to be determined at trial.

165. Additionally, the Illinois State Government is entitled to the maximum penalty for each and every violation alleged herein.

Count XIII
Illinois Insurance Claims Fraud Prevention Act

740 Ill. Comp. Stat. §§ 92/1

166. Relator realleges and incorporates by reference the allegations contained in paragraphs above as though fully set forth herein.

167. This is a claim for treble damages and penalties under the Illinois Insurance Claims Fraud Prevention Act.

168. Defendants knowingly caused the presentation of false or fraudulent claims to Illinois private insurers for payment or approval.

169. Relator cannot now identify all of the false claims for payment that Defendants' conduct caused, as numerous separate entities across the state presented the false claims. Relator has no control over such entities and no access to records they possess.

170. Illinois private insurers, unaware of the falsity of the claims that Defendants caused to be made, paid and continue to pay the claims that would not be paid but for Defendants' illegal conduct.

171. Defendants have damaged, and continue to damage, the State of Illinois in a substantial amount to be determined at trial.

172. Additionally, the Illinois State Government is entitled to the maximum penalty for each and every violation alleged herein.

Count XIV
Indiana False Claims & Whistleblower Protection Law
Ind. Code Ann. §§ 5-11-5.5-2(b)(1)–(2)

173. Relator realleges and incorporates by reference the allegations contained in paragraphs above as though fully set forth herein.

174. This is a claim for treble damages and penalties under the Indiana False Claims & Whistleblower Protection Law.

175. Defendants knowingly caused the presentation of false or fraudulent claims to the Indiana State Government for payment or approval.

176. Relator cannot now identify all of the false claims for payment that Defendants' conduct caused, as numerous separate entities across the state presented the false claims. Relator has no control over such entities and no access to records they possess.

177. The Indiana State Government, unaware of the falsity of the claims that Defendants caused to be made, paid and continues to pay the claims that would not be paid but for Defendants' illegal conduct.

178. Defendants have damaged, and continue to damage, the State of Indiana in a substantial amount to be determined at trial.

179. Additionally, the Indiana State Government is entitled to the maximum penalty for each and every violation alleged herein.

Count XV
Iowa False Claims Act
Iowa Code §§ 685.2(1)(a)-(b)

180. Relator realleges and incorporates by reference the allegations contained in paragraphs above as though fully set forth herein.

181. This is a claim for treble damages and penalties under the Iowa False Claims Act.

182. Defendants knowingly caused the presentation of false or fraudulent claims to the Iowa State Government for payment or approval.

183. Relator cannot now identify all of the false claims for payment that Defendants' conduct caused, as numerous separate entities across the state presented the false claims. Relator has no control over such entities and no access to records they possess.

184. The Iowa State Government, unaware of the falsity of the claims that Defendants caused to be made, paid and continues to pay the claims that would not be paid but for Defendants' illegal conduct.

185. Defendants have damaged, and continue to damage, the State of Iowa in a substantial amount to be determined at trial.

186. Additionally, the Iowa State Government is entitled to the maximum penalty for each and every violation alleged herein.

Count XVI
Louisiana Medical Assistance Programs Integrity Law
La. Rev. Stat. §§ 46:438.3(A)-(B)

187. Relator realleges and incorporates by reference the allegations contained in paragraphs above as though fully set forth herein.

188. This is a claim for treble damages and penalties under the Louisiana Medical Assistance Programs Integrity Law.

189. Defendants knowingly caused the presentation of false or fraudulent claims to the Louisiana State Government for payment or approval.

190. Relator cannot now identify all of the false claims for payment that Defendants' conduct caused, as numerous separate entities across the state presented the false claims. Relator has no control over such entities and no access to records they possess.

191. The Louisiana State Government, unaware of the falsity of the claims that Defendants caused to be made, paid and continues to pay the claims that would not be paid but for Defendants' illegal conduct.

192. Defendants have damaged, and continue to damage, the State of Louisiana in a substantial amount to be determined at trial.

193. Additionally, the Louisiana State Government is entitled to the maximum penalty for each and every violation alleged herein.

Count XVII
Maryland False Health Claims Act
Md. Code Ann., Health-Gen. §§ 2-602(a)(1)-(2)

194. Relator realleges and incorporates by reference the allegations contained in paragraphs above as though fully set forth herein.

195. This is a claim for treble damages and penalties under the Maryland False Health Claims Act.

196. Defendants knowingly caused the presentation of false or fraudulent claims to the Maryland State Government for payment or approval.

197. Relator cannot now identify all of the false claims for payment that Defendants' conduct caused, as numerous separate entities across the state presented the false claims. Relator has no control over such entities and no access to records they possess.

198. The Maryland State Government, unaware of the falsity of the claims that Defendants caused to be made, paid and continues to pay the claims that would not be paid but for Defendants' illegal conduct.

199. Defendants have damaged, and continue to damage, the State of Maryland in a substantial amount to be determined at trial.

200. Additionally, the Maryland State Government is entitled to the maximum penalty for each and every violation alleged herein.

Count XVIII
Massachusetts False Claims Law
Mass. Gen. Laws ch. 12, §§ 5B(a)(1)-(2)

201. Relator realleges and incorporates by reference the allegations contained in paragraphs above as though fully set forth herein.

202. This is a claim for treble damages and penalties under the Massachusetts False Claims Law.

203. Defendants knowingly caused the presentation of false or fraudulent claims to the Massachusetts State Government for payment or approval.

204. Relator cannot now identify all of the false claims for payment that Defendants' conduct caused, as numerous separate entities across the state presented the false claims. Relator has no control over such entities and no access to records they possess.

205. The Massachusetts State Government, unaware of the falsity of the claims that Defendants caused to be made, paid and continues to pay the claims that would not be paid but for Defendants' illegal conduct.

206. Defendants have damaged, and continue to damage, the State of Massachusetts in a substantial amount to be determined at trial.

207. Additionally, the Massachusetts State Government is entitled to the maximum penalty for each and every violation alleged herein.

Count XIX
Michigan Medicaid False Claims Act
Mich. Comp. Laws §§ 400.601

208. Relator realleges and incorporates by reference the allegations contained in paragraphs above as though fully set forth herein.

209. This is a claim for treble damages and penalties under the Michigan Medicaid False Claims Act.

210. Defendants knowingly caused the presentation of false or fraudulent claims to the Michigan State Government for payment or approval.

211. Relator cannot now identify all of the false claims for payment that Defendants' conduct caused, as numerous separate entities across the state presented the false claims. Relator has no control over such entities and no access to records they possess.

212. The Michigan State Government, unaware of the falsity of the claims that Defendants caused to be made, paid and continues to pay the claims that would not be paid but for Defendants' illegal conduct.

213. Defendants have damaged, and continue to damage, the State of Michigan in a substantial amount to be determined at trial.

214. Additionally, the Michigan State Government is entitled to the maximum penalty for each and every violation alleged herein.

Count XX
Minnesota False Claims Act
Minn. Stat. §§ 15C.02(a)(1)-(2)

215. Relator realleges and incorporates by reference the allegations contained in paragraphs above as though fully set forth herein.

216. This is a claim for treble damages and penalties under the Minnesota False Claims Act.

217. Defendants knowingly caused the presentation of false or fraudulent claims to the Minnesota State Government for payment or approval.

218. Relator cannot now identify all of the false claims for payment that Defendants' conduct caused, as numerous separate entities across the state presented the false claims. Relator has no control over such entities and no access to records they possess.

219. The Minnesota State Government, unaware of the falsity of the claims that Defendants caused to be made, paid and continues to pay the claims that would not be paid but for Defendants' illegal conduct.

220. Defendants have damaged, and continue to damage, the State of Minnesota in a substantial amount to be determined at trial.

221. Additionally, the Minnesota State Government is entitled to the maximum penalty for each and every violation alleged herein.

Count XXI
Montana False Claims Act
Mont. Code Ann. §§ 17-8-403(1)(a)-(b)

222. Relator realleges and incorporates by reference the allegations contained in paragraphs above as though fully set forth herein.

223. This is a claim for treble damages and penalties under the Montana False Claims Act.

224. Defendants knowingly caused the presentation of false or fraudulent claims to the Montana State Government for payment or approval.

225. Relator cannot now identify all of the false claims for payment that Defendants' conduct caused, as numerous separate entities across the state presented the false claims. Relator has no control over such entities and no access to records they possess.

226. The Montana State Government, unaware of the falsity of the claims that Defendants caused to be made, paid and continues to pay the claims that would not be paid but for Defendants' illegal conduct.

227. Defendants have damaged, and continue to damage, the State of Montana in a substantial amount to be determined at trial.

228. Additionally, the Montana State Government is entitled to the maximum penalty for each and every violation alleged herein.

Count XXII
Nevada False Claims Act
Nev. Rev. Stat. Ann. §§ 357.040(1)(a)-(b)

229. Relator realleges and incorporates by reference the allegations contained in paragraphs above as though fully set forth herein.

230. This is a claim for treble damages and penalties under the Nevada False Claims Act.

231. Defendants knowingly caused the presentation of false or fraudulent claims to the Nevada State Government for payment or approval.

232. Relator cannot now identify all of the false claims for payment that Defendants' conduct caused, as numerous separate entities across the state presented the false claims. Relator has no control over such entities and no access to records they possess.

233. The Nevada State Government, unaware of the falsity of the claims that Defendants caused to be made, paid and continues to pay the claims that would not be paid but for Defendants' illegal conduct.

234. Defendants have damaged, and continue to damage, the State of Nevada in a substantial amount to be determined at trial.

235. Additionally, the Nevada State Government is entitled to the maximum penalty for each and every violation alleged herein.

Count XXIII
New Jersey False Claims Act
N.J. Stat. §§ 2A:32C-3(a)-(b)

236. Relator realleges and incorporates by reference the allegations contained in paragraphs above as though fully set forth herein.

237. This is a claim for treble damages and penalties under the New Jersey False Claims Act.

238. Defendants knowingly caused the presentation of false or fraudulent claims to the New Jersey State Government for payment or approval.

239. Relator cannot now identify all of the false claims for payment that Defendants' conduct caused, as numerous separate entities across the state presented the false claims. Relator has no control over such entities and no access to records they possess.

240. The New Jersey State Government, unaware of the falsity of the claims that Defendants caused to be made, paid and continues to pay the claims that would not be paid but for Defendants' illegal conduct.

241. Defendants have damaged, and continue to damage, the State of New Jersey in a substantial amount to be determined at trial.

242. Additionally, the New Jersey State Government is entitled to the maximum penalty for each and every violation alleged herein.

Count XXIV
New Mexico Medicaid False Claims Act
N.M. Stat. Ann. §§ 27-14-4(A) & (C)

243. Relator realleges and incorporates by reference the allegations contained in paragraphs above as though fully set forth herein.

244. This is a claim for treble damages and penalties under the New Mexico Medicaid False Claims Act.

245. Defendants knowingly caused the presentation of false or fraudulent claims to the New Mexico State Government for payment or approval.

246. Relator cannot now identify all of the false claims for payment that Defendants' conduct caused, as numerous separate entities across the state presented the false claims. Relator has no control over such entities and no access to records they possess.

247. The New Mexico State Government, unaware of the falsity of the claims that Defendants caused to be made, paid and continues to pay the claims that would not be paid but for Defendants' illegal conduct.

248. Defendants have damaged, and continue to damage, the State of New Mexico in a substantial amount to be determined at trial.

249. Additionally, the New Mexico State Government is entitled to the maximum penalty for each and every violation alleged herein.

Count XXV
New York False Claims Act
N.Y. State Fin. §§ 189(1)(a)-(b)

250. Relator realleges and incorporates by reference the allegations contained in paragraphs above as though fully set forth herein.

251. This is a claim for treble damages and penalties under the New York False Claims Act.

252. Defendants knowingly caused the presentation of false or fraudulent claims to the New York State Government for payment or approval.

253. Relator cannot now identify all of the false claims for payment that Defendants' conduct caused, as numerous separate entities across the state presented the false claims. Relator has no control over such entities and no access to records they possess.

254. The New York State Government, unaware of the falsity of the claims that Defendants caused to be made, paid and continues to pay the claims that would not be paid but for Defendants' illegal conduct.

255. Defendants have damaged, and continue to damage, the State of New York in a substantial amount to be determined at trial.

256. Additionally, the New York State Government is entitled to the maximum penalty for each and every violation alleged herein.

Count XXVI
North Carolina False Claims Act
N.C. Gen. Stat. §§ 1-607(a)(1)-(2)

257. Relator realleges and incorporates by reference the allegations contained in paragraphs above as though fully set forth herein.

258. This is a claim for treble damages and penalties under the North Carolina False Claims Act.

259. Defendants knowingly caused the presentation of false or fraudulent claims to the North Carolina State Government for payment or approval.

260. Relator cannot now identify all of the false claims for payment that Defendants' conduct caused, as numerous separate entities across the state presented the false claims. Relator has no control over such entities and no access to records they possess.

261. The North Carolina State Government, unaware of the falsity of the claims that Defendants caused to be made, paid and continues to pay the claims that would not be paid but for Defendants' illegal conduct.

262. Defendants have damaged, and continue to damage, the State of North Carolina in a substantial amount to be determined at trial.

263. Additionally, the North Carolina State Government is entitled to the maximum penalty for each and every violation alleged herein.

Count XXVII
Oklahoma Medicaid False Claims Act
Okla. Stat. tit. 63 §§ 5053.1(B)(1)-(2)

264. Relator realleges and incorporates by reference the allegations contained in paragraphs above as though fully set forth herein.

265. This is a claim for treble damages and penalties under the Oklahoma Medicaid False Claims Act.

266. Defendants knowingly caused the presentation of false or fraudulent claims to the Oklahoma State Government for payment or approval.

267. Relator cannot now identify all of the false claims for payment that Defendants' conduct caused, as numerous separate entities across the state presented the false claims. Relator has no control over such entities and no access to records they possess.

268. The Oklahoma State Government, unaware of the falsity of the claims that Defendants caused to be made, paid and continues to pay the claims that would not be paid but for Defendants' illegal conduct.

269. Defendants have damaged, and continue to damage, the State of Oklahoma in a substantial amount to be determined at trial.

270. Additionally, the Oklahoma State Government is entitled to the maximum penalty for each and every violation alleged herein.

Count XXVIII
Rhode Island False Claims Act
R.I. Gen. Laws §§ 9-1.1-3(a)(1)–(2)

271. Relator realleges and incorporates by reference the allegations contained in paragraphs above as though fully set forth herein.

272. This is a claim for treble damages and penalties under the Rhode Island False Claims Act.

273. Defendants knowingly caused the presentation of false or fraudulent claims to the Rhode Island State Government for payment or approval.

274. Relator cannot now identify all of the false claims for payment that Defendants' conduct caused, as numerous separate entities across the state presented the false claims. Relator has no control over such entities and no access to records they possess.

275. The Rhode Island State Government, unaware of the falsity of the claims that Defendants caused to be made, paid and continues to pay the claims that would not be paid but for Defendants' illegal conduct.

276. Defendants have damaged, and continue to damage, the State of Rhode Island in a substantial amount to be determined at trial.

277. Additionally, the Rhode Island State Government is entitled to the maximum penalty for each and every violation alleged herein.

Count XXIX
Tennessee False Claims Act and Tennessee Medicaid False Claims Act
Tenn. Code Ann. §§ 4-18-103(a)(1)–(2) and §§ 71-5-182(a)(1)(A)–(B)

278. Relator realleges and incorporates by reference the allegations contained in paragraphs above as though fully set forth herein.

279. This is a claim for treble damages and penalties under Tennessee False Claims Act and Tennessee Medicaid False Claims Act.

280. Defendants knowingly caused the presentation of false or fraudulent claims to the Tennessee State Government for payment or approval.

281. Relator cannot now identify all of the false claims for payment that Defendants' conduct caused, as numerous separate entities across the state presented the false claims. Relator has no control over such entities and no access to records they possess.

282. The Tennessee State Government, unaware of the falsity of the claims that Defendants caused to be made, paid and continues to pay the claims that would not be paid but for Defendants' illegal conduct.

283. Defendants have damaged, and continue to damage, the State of Tennessee in a substantial amount to be determined at trial.

284. Additionally, the Tennessee State Government is entitled to the maximum penalty for each and every violation alleged herein.

Count XXX
Texas Medicaid Fraud Prevention Law
Tex. Hum. Res. Code Ann. § 36.002

285. Relator realleges and incorporates by reference the allegations contained in paragraphs above as though fully set forth herein.

286. This is a claim for treble damages and penalties under the Texas Medicaid Fraud Prevention Law.

287. Defendants knowingly caused the presentation of false or fraudulent claims to the Texas State Government for payment or approval.

288. Relator cannot now identify all of the false claims for payment that Defendants' conduct caused, as numerous separate entities across the state presented the false claims. Relator has no control over such entities and no access to records they possess.

289. The Texas State Government, unaware of the falsity of the claims that Defendants caused to be made, paid and continues to pay the claims that would not be paid but for Defendants' illegal conduct.

290. Defendants have damaged, and continue to damage, the State of Texas in a substantial amount to be determined at trial.

291. Additionally, the Texas State Government is entitled to the maximum penalty for each and every violation alleged herein.

Count XXXI
Vermont False Claims Act
31 Vermont Stats. Ann., Ch. 7, Subch. 8, §§ 630

292. Relator realleges and incorporates by reference the allegations contained in paragraphs above as though fully set forth herein.

293. This is a claim for treble damages and penalties under the Vermont False Claims Act.

294. Defendants knowingly caused the presentation of false or fraudulent claims to the Vermont State Government for payment or approval.

295. Relator cannot now identify all of the false claims for payment that Defendants' conduct caused, as numerous separate entities across the state presented the false claims. Relator has no control over such entities and no access to records they possess.

296. The Vermont State Government, unaware of the falsity of the claims that Defendants caused to be made, paid and continues to pay the claims that would not be paid but for Defendants' illegal conduct.

297. Defendants have damaged, and continue to damage, the State of Vermont in a substantial amount to be determined at trial.

298. Additionally, the Vermont State Government is entitled to the maximum penalty for each and every violation alleged herein.

Count XXXII
Virginia Fraud Against Taxpayers Act
Va. Code Ann. §§ 8.01-216.3(A)(1)–(2)

299. Relator realleges and incorporates by reference the allegations contained in paragraphs above as though fully set forth herein.

300. This is a claim for treble damages and penalties under the Virginia Fraud Against Taxpayers Act.

301. Defendants knowingly caused the presentation of false or fraudulent claims to the Virginia State Government for payment or approval.

302. Relator cannot now identify all of the false claims for payment that Defendants' conduct caused, as numerous separate entities across the state presented the false claims. Relator has no control over such entities and no access to records they possess.

303. The Virginia State Government, unaware of the falsity of the claims that Defendants caused to be made, paid and continues to pay the claims that would not be paid but for Defendants' illegal conduct.

304. Defendants have damaged, and continue to damage, the State of Virginia in a substantial amount to be determined at trial.

305. Additionally, the Virginia State Government is entitled to the maximum penalty for each and every violation alleged herein.

Count XXXIII
Washington State Medicaid Fraud False Claims Act
Wash. Rev. Code §§ 74.66.020(1)(a)–(b)

306. Relator realleges and incorporates by reference the allegations contained in paragraphs above as though fully set forth herein.

307. This is a claim for treble damages and penalties under the Washington State Medicaid Fraud False Claims Act.

308. Defendants knowingly caused the presentation of false or fraudulent claims to the Washington State Government for payment or approval.

309. Relator cannot now identify all of the false claims for payment that Defendants' conduct caused, as numerous separate entities across the state presented the false claims. Relator has no control over such entities and no access to records they possess.

310. The Washington State Government, unaware of the falsity of the claims that Defendants caused to be made, paid and continues to pay the claims that would not be paid but for Defendants' illegal conduct.

311. Defendants have damaged, and continue to damage, the State of Washington in a substantial amount to be determined at trial.

312. Additionally, the Washington State Government is entitled to the maximum penalty for each and every violation alleged herein.

Count XXXIV
District of Columbia False Claims Act
D.C. Code §§ 2-381.02(a)(1)–(2)

313. Relator realleges and incorporates by reference the allegations contained in paragraphs above as though fully set forth herein.

314. This is a claim for treble damages and penalties under the District of Columbia False Claims Act.

315. Defendants knowingly caused the presentation of false or fraudulent claims to the District of Columbia Government for payment or approval.

316. Relator cannot now identify all of the false claims for payment that Defendants' conduct caused, as numerous separate entities across the District of Columbia presented the false claims. Relator has no control over such entities and no access to records they possess.

317. The District of Columbia Government, unaware of the falsity of the claims that Defendants caused to be made, paid and continues to pay the claims that would not be paid but for Defendants' illegal conduct.

318. Defendants have damaged, and continue to damage, the District of Columbia in a substantial amount to be determined at trial.

319. Additionally, the District of Columbia Government is entitled to the maximum penalty for each and every violation alleged herein.

XI. PRAYER

WHEREFORE, Relator prays for judgment against Defendants as follows:

1. That Defendants cease and desist from violating 31 U.S.C. §§ 3729 *et seq*., and the analogous State statutes set forth above;

2. That this Court enter judgment against Defendants in an amount equal to three times the amount of damages the United States and the States have sustained because of Defendants' actions, plus the maximum civil penalty permitted for each violation of the Federal False Claims Act or of the analogous State statutes;

3. That Relator be awarded the maximum amount allowed pursuant to § 3730(d) of the False Claims Act and the equivalent provisions of the State statutes set forth above;

4. That Relator be awarded all fees, costs, and expenses incurred in connection with this action, including attorneys' fees, costs, and expenses; and

5. That Relator recover such other relief as the Court deems just and proper.

XII. DEMAND FOR JURY TRIAL

Pursuant to Rule 38 of the Federal Rules of Civil Procedure, Relator hereby demands a trial by jury.

Respectfully submitted,

YOUMAN & CAPUTO, LLC

Dated: July 3, 2021 BY: _____

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